



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

VIA FEDERAL EXPRESS

October 28, 2004

Gary Henry, Co-owner
5768 Brier Ridge Road
West Union, OH 45693

WARNING LETTER CIN-05-22529

Dear Mr. Henry:

From 5/25/2004 – 5/27/2004 a Consumer Safety Officer (CSO) from the Food and Drug Administration (FDA) conducted an inspection of your farm located in West Union, OH. The investigation found serious violations of the Federal Food, Drug, and Cosmetic Act (the Act).

The CSO collected a sample of bulk medicated feed that you manufacture and feed to your sheep (Sample #273604). Analysis of that sample revealed the presence of the following drugs:

Drug	Concentration
Lasalocid	229 g/ton
Oxytetracycline	33.1 g/ton

The investigation found that your use of the medicated premixes Bovatec 68 (Lasalocid) and Terramycin 50 (Oxytetracycline) in making this medicated feed did not conform to their approvals. The limit for Lasalocid in sheep feed is 20-30 grams/ton (21 CFR 558.311(e)(1)(viii)). The limit for Oxytetracycline in sheep feed for improved feed efficiency is 10-20 grams/ton (21 CFR 558.450(d)(1)(i)). For this reason, the drugs are unsafe under section 512 of the Act and adulterated within the meaning of section 501(a)(5) of the Act. In addition, the combination of these drugs is not approved for use in feed for sheep or at these levels. Therefore, the combination drug is also unsafe under section 512 of the Act and adulterated within the meaning of section 501(a)(5) of the Act. The medicated feed you manufactured is unsafe under Section 512(a)(2) of the Act because it bears or contains an unapproved new animal drug and new animal drugs that do not conform to approved applications. The feed is thus adulterated under 501(a)(6) of the Act.

Your medicated feed is further adulterated under section 501(a)(2)(B) because you have not complied with the current good manufacturing practice (GMP) regulations for medicated feeds (21 CFR 225). Examples of your failure to follow the GMPs include:

- You do not have a measuring device that is adequate to measure the amounts of medicated premix you are adding to your feed (21 CFR 225.130).
- You do not have records identifying the formula and date of mixing (21 CFR 225.202).

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to correct the violations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

The violations listed above are not intended to be an all-inclusive list. It is your responsibility to assure that your operations are in compliance with the law.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be addressed to Food and Drug Administration, 6751 Steger Drive, Cincinnati, OH 45237-3097, Attention: Stephen J. Rabe, Compliance Officer, 513-679-2700 ext 163.

Sincerely,

A handwritten signature in black ink, appearing to read "Carol A. Heppe", written in a cursive style.

Carol A. Heppe
District Director
Cincinnati District Office